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PTC/SB/33 (07-05)
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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number Docket Number (Optional) PRE-APPEAL BRIEF REQUEST FOR REVIEW 5828US BX2009T01740 (3712044-00440) I hereby certify that this correspondence is being deposited with the Application Number Filed United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for July 17, 2003 10/624.150 Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] First Named Inventor Robert W. Childers, et al. Signature Art Unit Examiner Typed or printed 3767 Laura C. Schell name, Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request. This request is being filed with a notice of appeal. The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided. I am the applicant/inventor. Signature assignee of record of the entire interest See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. Jason J. Novak (Form PTO/SB/96) Typed or printed name х attorney or agent of record. 312-558-5069 65,774 Registration number ___ Telephone number attorney or agent acting under 37 CFR 1.34. October 22, 2010 Registration number if acting under 37 CFR 1.34 ___ Date

This collection of information is required by 35 LIS.C. 132. The information is required to obtain or retain a benefit by the public which is not fee (and by the LISET) to process) an application. Conditionality is govered by 55 LIS.C. 122 and 37 CFR 111, 11.4 and 41.6. This collection is estimated to private by complete, including gathering preparing, and submitting the completed application form to the LISETO. Time will very depending upon the individual case. Any comments on the amount of time you require to complete its form and/or supplessions for reducing this busines, should be set to the Chef LISETO. The will be set to the Chef LISETO. The will be supplessed to the control of the completed of the comments on the set of the Chef LISETO. The control of the your counters to the control of the your posterior of the comments on the comments of the

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required,

Submit multiple forms if more than one signature is required, see below*.

forms are submitted.

*Total of _

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Robert W. Childers, et al.

Appl. No.: 10/624,150 Conf. No.: 5656

Filed: July 17, 2003

Title: SYSTEM AND METHOD FOR PERFORMING PERITONEAL DIALYSIS

Art Unit: 3767

Examiner: Laura C. Schell

Docket No.: 5828US BX2009T01740 (3712044-00440)

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Dear Examiner:

Introduction

This Request and following remarks are in response to the interpretation of the prior art and the misapplication of the law of obviousness in the final Office Action dated July 22, 2010. Applicants respectfully submit that such interpretation and application rise to the level of clear error, making this case proper for pre-appeal review. The Request is filed contemporaneously with form PTO/SB/31, "Pre-Appeal Brief Request for Review" and form PTO/SB/31, "Notice of Appeal." Please charge Deposit Account No. 02-1818 for the Notice of Appeal fee set forth under 37 C.F.R. §41.20(b)(1) and any other fees connected to the request.

Claims 1 to 30 are pending in the application. In the Office Action, Claims 1 to 30 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 6,666,842 to Sakai ("Sakai") in view of "Innovative Peritoneal Dialysis: Flow-Thru and Dialysate Regeneration," by Martin Roberts et al. ("Roberts"). Applicants respectfully submit that Claims 1 to 30 are not obvious in view of the present combination of references cited in the final Office Action.

Section 103 rejection of Claims 1 to 12 and 24 to 30

Regarding the rejection of Claims 1 to 12 and 24 to 30, Applicants respectfully submit that the combination of Sakai and Roberts fails to disclose or suggest a system for providing peritoneal dialysis to a patient, the system comprising a fluid circuit/loop configured to circulate dialysate into, through and out of a peritoneal cavity of the patient at an outflow rate from the

peritoneal cavity greater than an inflow rate to the peritoneal cavity, and a cycler configured to drain dialysate at a discharge rate substantially/approximately equal to a difference between the outflow rate and the inflow rate, effective to circulate the dialysate a plurality of times along the fluid loop prior to discharge as recited, in part, by independent Claims 1 and 24.

In support of the obviousness rejection, the final Office Action cited page 377, column 1, second paragraph of *Roberts*, which discusses an alternative flow-through method that involves the use of fresh dialysate for inflow, while fluid in the patient's peritoneum is recirculated at a high flow rate. No value for the *high* flow rate is specified in the cited paragraph of *Roberts*, but the first paragraph in column 1 of page 377 discusses recirculation rates of 100 ml/min or 200 ml/min. Page 377, column 1, second paragraph of *Roberts* does however indicate that an inflow flow rate (feed rate of fresh fluid into the recirculation loop) can be 30 ml/min. *Most importantly*, the passage says, "the outflow of the spent peritoneal dialysate would be adjusted to the inflow." Applicants submit that this statement means that the outflow (discharge rate) is set to *match* the inflow (feed rate). As evidence, Applicants direct the Patent Office to page 374, column 2, second paragraph (also cited in the Office Action) and Figure 7, reproduced below, of *Roberts* that shows a similar configuration to the peritoneal dialysis system described on page 377 except that the recirculation loop of Figure 7 has a hemofilter.

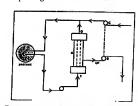


Figure 7. Flow-thru peritoneal dialysis and ultrafitration.¹² Reprinted with permission from Kraus MA et al., Dial Transplant 12: 385, 1963.

Regarding Figure 7, page 374 of *Roberts* discloses that the recirculating rate is set at 200 ml/min. The inflow (feed rate) and outflow (discharge rate) rates are *matched* or "adjusted" to be the same, i.e., to 36 ml/min. It should be appreciated that the spent dialysate outflow of both the cited passage at page 377 of *Roberts* and Figure 7 at page 374 of *Roberts* are analogous to the

discharge fluid path of Claims 1 and 24. Since feed and discharge rates are matched, the amount of fluid introduced into the system must equal the amount of fluid discharging the system.

Roberts therefore teaches a different flow regime than that of independent Claims 1 and 24, namely, a balance of feed and discharge rates. While Roberts discloses matching feed and discharge rates from the fluid circuit, Roberts does not disclose outflow rates greater than inflow rates. Roberts therefore fails to disclose a fluid circuit/loop configured to circulate dialysate into, through and out of a peritoneal cavity of the patient at an outflow rate from the peritoneal cavity greater than an inflow rate to the peritoneal cavity as recited by Claims 1 and 24.

Moreover, since the feed and discharge rates of *Roberts* are matched, the inflow rate into the patient and the outflow rate from the patient must also be equal. *Roberts* therefore <u>fails to suggest</u> an <u>outflow rate from the peritoneal cavity greater than an inflow rate</u> to the peritoneal cavity as recited by Claims 1 and 24.

Roberts also fails to teach or suggest a cycler that drains dialysate at a discharge rate substantially/approximately equal to a difference between the outflow rate and the inflow rate as recited, in part, by independent Claims 1 and 24. As discussed above, Roberts simply teaches a discharge rate matching a feed rate. Roberts however does not teach an outflow rate greater than an inflow rate and a discharge rate equal to the difference between the inflow and outflow rates.

Roberts, by contrast, relies on synchronized feed/discharge rates and inflow/outflow rates to achieve circulation. Since feed and discharge rates are equal, inflow rate must equal outflow rate to define a circulation rate. Roberts thus teaches a completely different flow scheme. Contrary to what the Examiner asserts, therefore, altering the flow rates in Roberts' system to match those of the claims would not have been obvious to one of ordinary skill in the art.

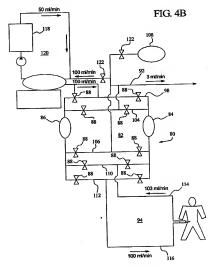
Applicants accordingly submit that Claims 1 to 12 and 24 to 30 are patentably distinguished over the combination of *Sakai* and *Roberts*, and the Examiner's rejection rises to the level of clear error.

Section 103 rejection of Claims 13 to 23

Regarding Claims 13 to 23, Applicants submit that Sakai and Roberts together fail to teach or suggest a fluid loop configured to circulate dialysate into, through and out of a peritoneal cavity via only a single loop of the fluid loop, the fluid loop including a first fluid line in communication with a dialysate supply, a second fluid line in communication with a discharge

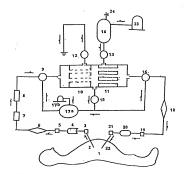
fluid path, a third line in communication with an outflow fluid path from the peritoneal cavity, and a fourth fluid line in communication with an inflow fluid path to the peritoneal cavity.

To support the obviousness rejection, the Patent Office relies on Sakai to teach the multiline fluid circuit of independent Claim 13. Applicants submit however that Sakai's system is fundamentally different than that of Claim 13. Claim 13, in essence, recites an outflow fluid path, inflow fluid path, a discharge fluid path and a dialysate supply, with a multi-line fluid circuit in communication with each of these elements. Applicants' FIG. 4B, for example, illustrates a circulation loop 94 made up of inflow and outflow paths 114 and 116. Circulation loop 94, and associated paths 114/116, is independent of the multi-line fluid circuit 82 that includes the fluid lines communicating with the inflow, outflow, discharge and supply paths.



Sakai, on the other hand, simply teaches a fluid loop with a discharge line, a supply line, and outflow and inflow fluid paths separated by a two-part filter (see FIG. 1 below). Sakai

teaches a fluid loop connected to a patient 1 via inflow and outflow catheters 2/22. The fluid loop includes an outflow path from the outflow catheter 2, through heater 6 and pre-filters 7/8, to filters 10/11. Inflow path leads from filters 10/11, to warmer 18, to inflow catheter 2. Discharge path (through pump 12) and supply path (though pump 13) are coupled to filters 10/11.



Sakai fails to teach either a third line in communication with an outflow path or a fourth line in communication with an inflow path. Since Sakai fails to teach the multi-line fluid circuit of Claim 13. Sakai cannot cure the deficiencies of Roberts.

Applicants accordingly submit that the combination of Sakai and Roberts does not render obvious Claims 13 to 23 and that Claims 13 to 23 are patentably distinguished over the combination of Sakai and Roberts, and the Examiner's rejection rises to the level of clear error.

Respectfully submitted,

K&L GATES LLP

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Dated: October 22, 2010